REMARKS

Reconsideration of the above-referenced patent application is respectfully requested in view of the foregoing amendments and remarks set forth herein. Applicant respectfully requests entry of the amendments herein as placing the application in better form for appeal.

Substance of Interview

A telephonic interview with the Examiner was held on July 1, 2009, and an Office Communication entitled "Interview Summary" dated July 6, 2009 was received. Applicant. While the latter indicates that agreement was reached, as indicated on the Continuation Sheet of the Interview Summary, possible ways of addressing the rejection based on the art were discussed, with the possibility of adding additional method steps or limiting the claims to beta(1,6) glucans or to detection of a specific fungal disease. It was agreed that Applicant would attempt to find solutions; however, no specific solution was agreed to as eliminating all previous grounds of rejection.

Claims 24 and 28 have been amended to clarify them, and claim 40 has been added which recites the terminology of claim 24. All three claims have added terminology of using an assay consisting essentially of using, which is consistent with Applicant's disclosed invention where the substances listed after this phrase are the only essential components that are used by Applicant in the specification. No new matter is added by these amendments.

In the Office Action of June 9, 2009, the Examiner took the following actions to which Applicant herein makes response: rejected clams 24 and 28 under 35 USC 102(b) as being anticipated by Wakshull et al. These rejections are traversed in application to the claims as amended, and consideration is requested of the patentability of claims 24, 28 and 40 now pending in the application.

Rejection of clams 24 and 28 under 35 USC 102(b) as being anticipated by Wakshull et al.

Applicant has reviewed the specification and Wakshull et al. again, and respectfully submits that Wakshull et al. neither teaches nor suggests the invention of claims 24 and 28 now pending herein.

As stated in Applicant's response filed April 11, 2007, Wakshull et al discloses methods of isolating β(1-3)-glucan or β(1-3)-glucan-containing organisms in a sample, utilizing binding agents such as lactosylceramide, galactosyl ceramide, globotriaosylceramide and asialoganglioside-GM1 (e.g., claim 4 of Wakshull et al.). These particular binding agents are mostly not antibodies, and when antibodies are used in Wakshull et al., they are used with an additional binding agent. Further Wakshull neither teaches nor suggests that this isolation or detection of organisms would also be useful for detecting the glucans in free form or in cell wall fragments.

Applicant also respectfully points out that Wakshull does not teach or suggest using "an antibody reactive with a fungal β(1-3) glucan – epitope and a fungal β(1-3)(1-6) – glucan epitope" as claimed by Applicant in pending claims 24 and 28. In fact, Applicant has not found any mentioned of fungal β(1-3)(1-6) – glucan epitopes in Wakshull et al.

A primary aspect differentiating Applicant's invention from that of Wakshull is that Applicant does not use a GalCer but only a mAb as the capture agent. Wakshull's method is dependent on the binding agent in order to be functional (page 5, line 11-14). In page 32 he describes the GalCer Capture and antibody detection of B-glucans in biological fluids. Here again, the plates need to be pre-coated with GalCer II even when antibodies are used. Similarly, in Example 7, where Wakshull compared the sensitivity of antibodies, they were used to detect soluble β(1-3) glucan which had been bound to GalCer (page 36, lines 22-26). Thus Wakshull neither teaches nor suggests assaying mucosal secretions or urine of the patient with a suspected invasive fungal infection with using an assay consisting essentially of using at least one antibody reactive with a fungal β(1-3) glucan – epitope and a fungal β(1-3)(1-6) – glucan epitope that is in free form or is available in cell wall fragments of fungi or on the cell surface of fungi.

On page 8, line 8, Wakshull talks about the GalCer's (binding agent) ability to capture B-glucan in different conformational status. Also, the sensitivity of his method depends on the B (1-3) glucan ability to specifically bind specific binding agents e.g.

GalCer (page 8, line 17-21). On page 36, line 7, he states: "The results shown in figure 6, demonstrate that GalCer captures only glucans having high molecular weight." Also, from example 4 on page 35, it is clear that there are differences in reactivity against the different binding agents.

Although Wakshull mentions different methods that are known in the art to detect this combination, including antibodies, it is important to point out that Wakshull neither teaches nor suggest assaying mucosal secretions or urine of the patient or diagnosis of a fungal infection in a patient comprising assaying mucosal secretions or urine of the patient as found in Applicant's claimed invention, nor evaluating the glucan levels as part of detection of an invasive fungal infection.

Using the invention herein, there is detection of invasive fungal invention by the use of antibodies reactive with both β(1-3) glucan and β(1-3)(1-6) glucan both in free form and/or available in cell wall fragments of fungi, and evaluation of the levels of the glucans. This is not suggested or taught by Wakshull. Applicant's detection also includes surface-localized antigens, which means that in addition to the free form, the invention detects the β-glucan present on the surface of intact yeast cells. The aim in the invention, which is not found in Wakshull, is to also take into account antigens, which would not be blurred by interference with high levels of host antibodies. Applicant has tested different antigens and no other combination shows the results disclosed by Appliant. Other β–glucans such as β(1-3)(1-4) and β(1-6) had been evaluated. It was evident that the best results were obtained with antibodies reactive with both β (1-3) glucan and β(1-3)(1-6) glucan both surface localized and in free form.

As stated in the specification, the use of free β(1-3) glucans as a laboratory marker for diagnosing deep fungal infections was already known in the art. But the novelty of the invention herein lies in the inclusion of the surface-localized specific β-glucans and in the direct detection of them via monoclonal antibodies as capture agents.

Applicant respectfully requests that if the Examiner determines that additional amendment of the claims pending herein would be useful in clarifying Applicant's invention, Applicant respectfully requests an appropriate Examiner's amendment of the claims.

Applicant therefore submits that claims 24 and 28 as amended are patentable under Section 102(b) over Wakshull et al.

New Claim

New claim 40 has been added as discussed above. Applicant respectfully submits that Wakshull neither teaches nor suggests anything about use of a fungal β(1-3)(1-6) – glucan epitope in free form or available in cell wall fragments of fungi or on the cell surface of fungi.

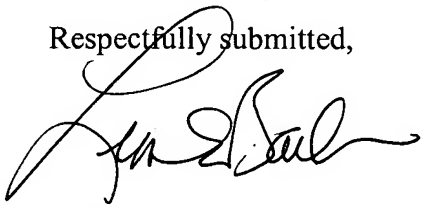
Conclusion

For all the foregoing reasons, claims 24, 28 and 40 are submitted to be fully patentably distinguished over the cited reference and in allowable condition. Favorable consideration is therefore requested.

It is believed that no fee is required for the presentation of this amendment. Any amounts that may be due for presentation of this amendment should be charged to Deposit Account No. 02-0825 of Applicant's attorney.

If any questions or issues remain, the resolution of which the Examiner feels would be advanced by a personal or telephonic conference with Applicant's attorney, the Examiner is invited to contact such attorney at the telephone number noted below.

Respectfully submitted,



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